Summary - 510(k) # **K062354**

SUBMITTER: Chattanooga Group,
A Division of Encore Medical, L.P.
4717 Adams Road
Hixson, TN 37343

JAN 26 2007

EXTABLISHMENT REGISTRATION: 1022819

CONTACT PERSON: Michael Treas
Manager of Regulatory Affairs
Phone: (423) 870-2281
Fax: (423) 870-7404

DATE PREPARED: October 20, 2006

DEVICE TRADE NAME: Vectra Genisys

CLASSIFICATION: Class II

PRODUCT CODES: IPF, IMG, GZJ, HCC, GZI, LIH

REGULATION NUMBERS AND COMMON NAMES:
21 CFR 890.5850- Stimulator, Muscle, Powered
21 CFR 890.5860- Ultrasound and muscle stimulator
21 CFR 882.5890- Transcutaneous electrical nerve stimulator for pain relief
21 CFR 882.5050- Biofeedback device
21 CFR 882.5810- External functional neuromuscular stimulator
21 CFR 876.5320- Non-implantable electrical continence device

PANELS: 89- Physical Medicine, 84- Neurology & 78- Gastroenterology

PREDICATE: Omnistim FX^2 – K945509
Omnistim FX^2 Pro – K945508

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Description: Vectra Genisys electrotherapy product lines offer clinicians a modular design of muscle stimulation, ultrasound, and biofeedback modalities in one combination device. These clinical product lines are designed to give the most treatment options in one compact and integrated package. The award winning design offers a 5 inch TFT LCD vibrant color display screen and hand held accessories.

Clinicians have a variety of choices to best suit the needs of the individual practice. Below is an overview of the system choices. The electrotherapy mode offers one of the largest selections of multiple waveforms cleared to market by the FDA. The numeric pain scales can be recorded with the patient data management system. The therapy system cart provides six concealed storage bins to conveniently house clinical essentials.

The electrotherapy module offers multiple waveforms; Interferrential, Premodulated, Asymmetrical Biphasic, Microcurrent, VMS-(Pulsed Mode, Burst Mode, and FR Mode), Russian, High Voltage Pulsed Current, Symmetrical Biphasic, Direct Current.

The dual frequency ultrasound module offers Pulsed and Continuous Duty Cycles (10%, 20%, 50%, and 100%), Low BNR (5:1), Four different size ultrasound applicators, 1cm^2, 2cm^2, 5 cm^2, and 10 cm^2.

The sEMG biofeedback module provides two channels of surface EMG. Feedback can be stored onto the sEMG Data Card. The sEMG features a clinician chosen trigger point that activates therapeutic stimulation. The sEMG feature is often used to treat stroke patients and for muscle re-education.

The online-guided assistance through Clinical Protocols and On-Board Indications to help guide therapy selections: electrotherapy waveform rationale, parameter selections, electrode placement images, ultrasound applicator recommendations.

The combination electrotherapy is used for the management of pain and muscle spasm. All functions of 1 or 3.3 MHz Ultrasound can be combined with Interferrential, Premodulated, Asymmetrical Biphasic, VMS-(Pulsed Mode, Burst Mode,), and High Voltage Pulsed Current.

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Declarations of Conformity

The Vectra Genisys devices are in compliance with the following FDA recognized consensus standards:

UL 60601-1: 2003, Standards for Medical Equipment Part 1: General Requirements for Safety, 1st Edition

IEC 60601-1-2: 2001, Medical Electrical Equipment Part 1 – 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests, 2nd Edition

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information was included in the submission.

Further Information

In the event that additional information is required, please contact:

Michael Treas
Manager of Regulatory Affairs
Chattanooga Group A Division of Encore Medical, L.P.
4717 Adams Road
Hixson, TN 37343-0489
U.S.A.
Telephone: (423) 870-2281
Fax: (423) 870-7404
E-mail: Michael_Treas@ChattGroup.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2007

Encore Medical, L.P.
Chattanooga Group
c/o Mr. Michael Treas
4717 Adams Road
Hixson, Tennessee 37343

Re: K062354
Trade Name: Vectra GENiSYS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: II
Product Code: IPF, GZJ, HCC, IMG, GZI
Dated: January 26, 2007
Received: January 26, 2007

Dear Mr. Treas:

This letter corrects our substantially equivalent letter of January 26, 2007. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K062354
Device Name: Vectra Genisys

Indications for Use: (Page 1 of 2)

For VMS-(Pulsed Mode, Burst Mode or FR Mode), Russian, Monophasic Hi-Volt (NMES) & Interferential and Premodulated (IFS)

Relaxation of Muscle Spasms
Prevention or retardation of disuse atrophy
Increasing local blood circulation
Muscle re-education
Maintaining or increasing range of motion
Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS-(Pulsed Mode, Burst Mode or FR Mode), Asymmetrical Biphasic (TENS), and Symmetrical Biphasic (TENS)

Symptomatic relief or management of chronic, intractable pain
Post-traumatic acute pain
Post-surgical acute pain

For FES

Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait

For DC Continuous Mode

Relaxation of muscle spasm

For EMG

To determination the activation timing of muscles for: a) retraining of muscle activation b) coordination of muscle activation
An indication of the force produced by muscle for control and maintenance of muscle contractions
Relaxation muscle training
Muscle re-education

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062354

Prescription Use ~~Over-The-Counter Use~~
(Per 21 CFR 801.109) (Optional Format 1-2-96)

510(k) Number K062354
Device Name: Vectra Genisys

Indications for Use: (Page 2 of 2)

For EMG triggered Stim
Stroke rehab by muscle re-education
Relaxation of muscle spasms
Prevention or retardation of disuse atrophy
Increase local blood circulation
Muscle re-education
Maintaining or increasing range of motion

For Ultrasound
Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:
1. Relief of pain, muscle spasms and joint contractures
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
a) Adhesive capsulitis
b) Bursitis with slight calcification
c) Myositis
d) Soft tissue injuries
e) Shortened tendons due to past injuries and scar tissues
3. Relief of sub-chronic and chronic pain and joint contractures resulting from:
a) Capsular tightness
b) Capsular scarring

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062354